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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY DOCKET NO
09/166,649	10/05/98	SCHMIDT A	56613/JPW/JM

EXAMINER	
O HARA, E	
ART UNIT	PAPER NUMBER
1646	5

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DATE MAILED: 06/10/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-57 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-57 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

DETAILED ACTION

1. Claims 1-57 are pending in the instant application.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13 and 15-29, drawn to a method for determining whether a compound is capable of inhibiting the interaction of a peptide with a receptor for advanced glycation end product, classified in class undeterminable, subclass undeterminable.

II. Claims 14 and 53-57, drawn to a compound of unspecified constitution, classified in class undeterminable, subclass undeterminable.

III. Claims 30 and 31, drawn to a method of assaying whether a compound of unspecified constitution can inhibit a peptide-receptor interaction in a transgenic animal, classified in class undeterminable, subclass undeterminable.

IV. Claims 32-52, drawn to a method of inhibiting the interaction of an advanced glycation end product with a receptor for advanced glycation end product in a subject, comprising administering to the subject an inhibitory compound of unspecified constitution, classified in class undeterminable, subclass undeterminable.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and each of inventions I , III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product that is invention II can be used in the invention of group I to inhibit a peptide-receptor interaction in vitro, or in the invention of group II by using a transgenic animal, or it can be used as a therapeutic agent as in the invention of group IV.

Inventions I, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions each require different starting materials and have different steps, methods and goals. Because these inventions are distinct for the reasons given above and the search required for each of the groups is not required for others, restriction for examination purposes as indicated is proper.

Election of Species

3. Claims 1-13, 15-31 and 49-52 are generic to a plurality of distinct species of:

a) **peptide:** carboxymethyl-modified, carboxymethyl-lysine-modified, and synthetic, as in claims 3, 4 and 5,

b) **derivatization of the peptide:** aryl, alkyl, acetyl, propyl, isopropyl, butyl, isobutyl, and carboxymethyl, as in claims 9-12,

c) **compound:** net negative charge, net positive charge, SRAGE, peptidomimetic, organic molecule, polypeptide, nucleic acid, inorganic molecule, less than 10,000 daltons, antibody, humanized, chimeric, primatized, mutated AGE and mutated RAGE, quinine, derivative of quinine, quinidine and derivative of quinidine as in claims 14-23 and 49-52.

Claims 37-43 and 53-56 are generic to a plurality of distinct species of **disease state:** diabetes, systemic lupus erythematosus, inflammatory lupus nephritis, amyloidoses, inflammation, obesity, advanced age and kidney failure.

Claim 33 is generic to a plurality of **subjects:** human, primate, mouse, rat and dog.

Claim 32 is generic to a plurality of **modes of administration:** intralesional, intraperitoneal, intramuscular injection, intravenous injection, infusion, liposome-mediated delivery, topical, nasal, oral, ocular and otic delivery.

Claims 45-48 are generic to a plurality of **carriers:** diluent, virus, liposome, microencapsule, polymer encapsulated cell, retroviral vector, time release implant, aerosol, intravenous, oral and topical carrier.

Applicant is required under 35 U.S.C. 121 to elect a single species from each of these seven groups of species of the invention that is elected for further examination on the merits:

1) peptide

2) derivitization of the peptide

3) compound

4) disease state

5) subjects

6) modes of administration

7) carriers,

even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that are elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should Applicant traverse on the ground that the species are not patently distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence of admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Upon allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species MPEP § 809.2 (a).

Applicant is advised that the reply to this requirement to be complete must include an election of the inventions to be examined and election of each of the species even though the requirement be traversed (37 C.F.R. 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached at (703) 308-4310.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800